

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michael B. ZEMEL et al.

Appl. No.: Not Yet Assigned

Confirmation No.: Not Yet Assigned

Filed: April 20, 2004

For: METHODS OF PROMOTING  
CALCIUM CONSUMPTION FOR  
WEIGHT LOSS

Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

Atty. Docket No.: 31894-199326

Customer No.:

26694

**Information Disclosure Statement**

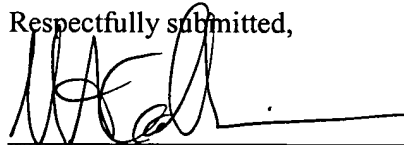
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants hereby notify the U.S. Patent and Trademark Office of the documents that are listed on the attached PTO/SB/08A forms. All of the listed references are of record in parent Application No. 10/066,057, except for A5 and A49 – A51, which are of record in related Application No. 10/017,568, where copies may be obtained in accordance with customary PTO practice. Applicants request that these documents be considered and listed on the face of any patent granted in this application.

Date: 4/20/04

Respectfully submitted,



Michael A. Gollin  
Registration No. 31,957  
VENABLE LLP  
P.O. Box 34385  
Washington, D.C. 20043-9998  
Telephone: (202) 344-4000  
Telefax: (202) 344-8300

+

+

+

+

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**Complete if Known**

Application Number	Not Yet Assigned
Filing Date	April 20, 2004
First Named Inventor	Michael B. ZEMEL et al.
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	31894-199326

Sheet	1	of	5
-------	---	----	---

[illegible][illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

**VENABLE**  
ATTORNEYS AT LAW

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	Not Yet Assigned
				Filing Date	April 20, 2004
				First Named Inventor	Michael B. ZEMEL et al.
				Group Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	31894-199326
Sheet	2	of	5		

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A10	BÖRJESON, M. [1976] "The aetiology of Obesity in Children, " Acta Paediatr Scan 65:279-87	
	A11	CARPER, JEAN [2000] "Amazing Food Facts That Astound the Experts, " USA Weekend, Aug. 18-20, 2000, p. 4	
	A12	CNN, "Zemel Weight Loss Story, March 30, 2000; and NATIONAL DAIRY COUNCIL, "Diary Foods May Help Control Weight Gain, " June 9, 2000, videotape	
	A13	COLINO, S., "Advanced Calcium, Lose Weight, avoid PMS and ward off cancer, all with one basic nutritional element, " Women's Sports & Fitness, March 2000, page 56	
	A14	DAVIS, J.; "Weight-Loss Tip: Add Extra Calcium to a Low-Fat Diet, Low-Fat Dairy Products May Help Weight Loss, Control," WebMDHealth, April 17, 2000 (printed from website), Publisher: 2000 Healtheon/WebMD	
	A15	FLEET, J.C. [1999] "Vitamin D. Receptors: Not Just in the Nucleus Anymore," Nutrition Reviews Vol. 57, No. 2, pp.60-2	
	A16	FLEURY, CHRISTOPHE, et al. [1997] "Unoupling Protein-2: a Novel Gene Linked to Obesity and Hyperinsulinemia," Nature Genetics 15:269-72	
	A17	Gimeno, R. et al. [1997] "Cloning and Characterization of an Uncoupling Protein Homolog: A Potential Molecular Mediator of Human Thermogenesis," Diabetes 46:900-06	
	A18	JONES, BRYNN H., et al. [1997] "Angiotensin II Increase Lipogenesis in 3T3-L1 and Human Adipose Cells," Endocrinology, Vol. 138, No. 4, pp. 1512-19	
	A19	KIM, JUNG HAN et al. [1996] "The Effects of Calcium Channel Blockade on Agouti-Induced Obesity", The FASEB Journal 10:1646-52	
	A20	LANGE, D., "The Calcium Diet", Allure, August 2000, page 84	

Examiner Signature	Date Considered
-----------------------	--------------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**VENABLE**  
ATTORNEYS AT LAW

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete if Known</b>	
	Application Number	Not Yet Assigned		
	Filing Date	April 20, 2004		
	First Named Inventor	Michael B. ZEMEL et al.		
	Group Art Unit	Not Yet Assigned		
	Examiner Name	Not Yet Assigned		
Sheet	3	of	5	Attorney Docket Number
				31894-199326

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A21	MASLOWSKA, M. et al. [1998] "Site Specific Binding of Acylation Stimulating Protein (ASP) in Human Adipose Tissue," Int. J. Obesity 22:S108 (P50)	
	A22	McCarty, L., "Got Milk, Lose Weight?," Remedy Magazine, March/April 2000, page 11	
	A23	MOLL, P.P., et al. [1991] "The Genetic and Environmental Sources of Body Mass Index Variability: The Muscatine Ponderosity Family Study," Am. J. Hum. Genet. 49:1243-55	
	A24	MUNDELL, E.J., "Trying to Lose Weight? Calcium May Help", Reuters health report, April 17, 2000, (printed from website), Publisher: Reuters Limited	
	A25	MYNATT, R.L., et al. [1997] "Combined Effects of Insulin Treatment and Adipose Tissue-Specific Agouti Expression on the Development of Obesity," Proc. Natl. Acad. Sci, USA 94:919-922	
	A26	NEMERE, I., et al. [1998] "Identification of a Membrane Receptor for 1, 25-Dihydroxyvitamin D <sub>3</sub> Which Mediates Rapid Activation of Protein Kinase C," J. of Bone and Mineral Research 13:1353-59	
	A27	PANTALONE, M., "Hello Calcium, Goodbye Fat," UT Agriculture, Fall 2000, Pages 5-7	
	A28	RABKIN, R., "Calcium Promotes Weight Loss," Family Circle, October 3, 2000, page 98	
	A29	RALOFF, J., "Calcium May Become a Dieter's Best Friend," Science News, April 29, 2000, page 277, Vol.157	
	A30	SHI, HANG, et al. [1999] "Role of the Sulfonylurea Receptor in Regulating Human Adipocyte Metabolism," The FASEB Journal 13:1833-38	
	A31	SHI, H. et al. [2000] "Effects of Dietary Calcium on Adipocyte Lipid Metabolism and Body Weight Regulation in Energy-Restricted Mice," FASEB J 14:555.3 (page A790)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**VENABLE**  
ATTORNEYS AT LAW

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	Not Yet Assigned	
			Filing Date	April 20, 2004	
			First Named Inventor	Michael B. ZEMEL et al.	
			Group Art Unit	Not Yet Assigned	
			Examiner Name	Not Yet Assigned	
Sheet	4	of	5	Attorney Docket Number	31894-199326

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A32	SHI, H. et al. [2000] "1, 25-Dihydroxyvitamin D (1, 25-(OH) <sub>2</sub> -D) Inhibits Uncoupling Protein 2 (UCP2) Expression in Human Adipocytes," Obesity Research 8(1):52S (O154)	
	A33	SHI, H. et al. [2001] "Effects of Dietary calcium on Adipocyte Lipid Metabolism and Body Weight Regulation in Energy-Restricted aP2-agouti Transgenic Mice," FASEB J 15:291-3 and 10.1096/fj.00-0584fje	
	A34	SHI, H. et al. [2001] "1α, 25-Dihydroxyvitamin D <sub>3</sub> Modulates Human Adipocyte Metabolism via Nongenomic Action," FASEB J 15:835.6 (page A1091)	
	A35	SMITH, S., "Functional Foods...Potential New Functional Qualities of Dairy Foods," NCC Newsletter, 2001, pages 34-5, Vol. 3, issue 2; Publisher: Nutrition in Complementary Care	
	A36	SOBEL, R.K. [2000] "Catching the Fat Bug," U.S. News & World Report p. 64	
	A37	SUMMERBELL, C.D., et al. [1998] "Randomised Controlled Trial of Novel, Simple, and Well Supervised Weight Reducing Diets in Outpatients," BMJ 317:1487-89	
	A38	Unknown, "5-Step Fat-Blasting Diet," Prevention Magazine, June 2000, page 151	
	A39	Unknown, "Calcium and Weight-Loss," Medizine, Jan-Feb-Mar 2001, page 52	
	A40	ZEMEL, M. et al. [1999] "Calcium and Calcium-Rich Dairy Products Reduce Body Fat," FASEB J 12:LB211	
	A41	ZEMEL, M. et al. [1999] "Synergism between Diet-induced Hyperinsulinemia and Adipocyte-Specific Agouti Expression," FASEB J 13:660.3 (page A873)	
	A42	ZEMEL, M., "Readers Want to Know," Bottom Line/Health, October 2000	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**VENABLE**  
ATTORNEYS AT LAW

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	Not Yet Assigned
		Filing Date	April 20, 2004
		First Named Inventor	Michael B. ZEMEL et al.
		Group Art Unit	Not Yet Assigned
		Examiner Name	Not Yet Assigned
Sheet	5	of	5
		Attorney Docket Number	31894-199326

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A43	ZEMEL, M. et al. [2001] "Effects of Calcium-Fortified Breakfast Cereal on Adiposity in a Transgenic Mouse Model of Obesity," FASEB J 15:480.7 (page A598)	
	A44	ZEMEL, M. B. et al. [2000] "Regulation of Adiposity by Dietary Calcium," The FASEB Journal, Vol. 14, No. 9, pp. 1132-7	
	A45	ZEMEL, P. et al. [2000] "Increasing Dietary Calcium and Dairy Product Consumption Reduces the Relative Risk of Obesity in Humans," Obesity Research 8(1):118 (HT-04)	
	A46	SANWA KAGAKU KENKYUSHO CO, "Stabilised Oligo Peptide Composition for Sleep-Improving Drug Containing Oligo-Peptide and Bovine Bone Powder as Calcium Salt, for Obesity Treatment, etc.," Database WPI, Section Ch, Week 199028, Derwent Publications Ltd., London, GB; Class B04, AN 1990-214417, XP002206900 & JP 02 145525 A, June 5, 1990 - abstract	
	A47	MEIJI SEIKA KAISHA, "Food Compound for Overweight Clients - Obtained by Blending Water Soluble Dietary Fibers and Insoluble Calcium Compound in Acidic Conditions, e.g., Gastric Juice," Database WPI, Section Ch, Week 199211, Derwent Publication Ltd., London, GB; Class D13, AN 1992-083488, XP002206898 & JP 04 023968 A, January 28, 1992 - abstract	
	A48	MEIJI SEIKA KAISHA, "Diet or Diabetic Food - Contains Water-Soluble Food Fiber, Preferably Arginic Acid (Salt), and Insoluble Calcium Compound," Database WPI, Section Ch, Week 199532, Derwent Publication Ltd., London, GB; Class B04, AN 1995-242723, XP002206899 & JP 07 147935 A, June 13, 1995 - abstract	
	A49	B. BOUILLON, et al., "Structure-Function Relationships In The Vitamin D Endocrine System," Endocrine Rev. (1995) pp. 200- 57, Vol. 16.	
	A50	A.W. NORMAN, "Receptor for 1 $\alpha$ ,25(OH) <sub>2</sub> D <sub>3</sub> : Past, Present, and Future," J. Bone. Miner. Res. (1998) pp. 1360-69, Vol. 13.	
	A51	A. NORMAN et al., "Demonstration That 1 $\beta$ ,25-Dihydroxyvitamin D <sub>3</sub> Is An Antagonist Of The Nongenomic But Genomic Biological Response And Biological Profile Of The Three A-Ring Diastereomers Of 1 $\alpha$ ,25-Dihydroxyvitamin D <sub>3</sub> ", J. Biol. Chem. (1993) pp. 20022-30, Vol. 268.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**VENABLE**  
ATTORNEYS AT LAW